

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Jean-Christophe AUDONNET et al.
Filed : Herewith
Serial No. : Divisional of 09/232,278
For : **FELINE POLYNUCLEOTIDE VACCINE FORMULA**

745 Fifth Avenue
New York, NY 10151

EXPRESS MAIL

Mailing Label Number: EL 742693338US

Date of Deposit: August 30, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to the Honorable Commissioner of Patents and Trademarks, Washington, DC 20231.

CHARLES B. JACKSON

(Typed or printed name of person mailing paper or fee)


(Signature of person mailing paper or fee)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Sir:

Before the issuance of the first Official Action, please amend the above-identified application as follows:

IN THE SPECIFICATION:

Please amend the specification without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

Page 1, line 1, please insert the following:

--This application is a divisional of prior application Serial No. 09/232,278, filed January 16, 1999 which is a continuation-in-part of copending International Application PCT/FR97/01315 having an international filing date of 15 July 1997, and designating the U.S. and claiming priority from French Application No. 96/09337, filed 19 July 1996. Reference is also made to the applications of Audonnet et al., Serial Nos 09/232,468, 09/232,477, 09/232,279, 09/232,479, and 09/232,478 and to the application of Rijsewijk et al. Serial No. 09/232,469, all filed July 19, 1996. All of the above-mentioned applications, as well as all documents cited herein and documents referenced or cited in documents cited herein, are hereby incorporated herein by reference. Vectors of vaccines or immunological compositions of the aforementioned applications, as well as of documents cited herein or documents referenced or cited in documents cited herein or portions of such vectors (e.g., one or more or all of regulatory sequences such as DNA for promoter, leader for secretion, terminator), may to the extent practicable with respect to the preferred host of this application, also be employed in the practice of this invention; and, DNA for vectors of vaccines or immunological compositions herein can be obtained from available sources and knowledge in the art, e.g., GeneBank, such that from this disclosure, no undue experimentation is required to make or use such vectors.--.

Page 1, line 37, please insert: --(See also U.S. Patent Nos. 5,846,946, 5,620,896, 5,643,578, 5,580,589, 5,589,466, 5,693,622, and 5,703,055; Science, 259:1745-49, 1993; Robinson et al., seminars in IMMUNOLOGY, 9:271-83, 1997; Luke et al., J. Infect. Dis. 175(1):91-97, 1997; Norman et al., Vaccine, 15(8):801-803, 1997; Bourne et al., The Journal of Infectious Disease, 173:800-7, 1996; and, note that generally a plasmid for a vaccine or immunological composition can comprise DNA encoding an antigen operatively linked to regulatory sequences which control expression or expression and secretion of the antigen from a host cell, e.g., a mammalian cell; for instance, from upstream to downstream, DNA for a

promoter, DNA for a eukaryotic leader peptide for secretion, DNA for the antigen, and DNA encoding a terminator.)--

Page 1, line 6, please amend as follows: --Associations of vaccines against certain feline viruses have already been proposed in the past---

Page 2, line 3, please amend as follows: --The invention therefore proposes to provide a multivalent vaccine formula which makes it possible to ensure vaccination against a number of feline pathogenic viruses.--

Page 7, line 23, please amend as follows: --Brief Description of the Drawings --.

Immediately after page 20 and before the first page of claims (page 21), if appropriate, please insert the enclosed pages identified as --Sequence Listing.--

Please accept the enclosed paper copy of the sequence listing (identical to the sequence listing submitted for parent application Serial No. 09/232,278), the required Statements under 37 C.F.R. § 1.821(f) and (g).

IN THE ABSTRACT:

Please insert the Abstract as attached hereto.

IN THE CLAIMS:

Please cancel claims 1-10 and add new claims 11-25 without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

--11. An immunogenic composition for inducing in a feline host an immunological response against feline immunodeficiency virus comprising at least one plasmid that contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins.

12. The immunogenic composition according to claim 11 which comprises a plasmid that contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env and gag and pro proteins.

13. The immunogenic composition according to claim 11 which comprises a first plasmid that contains and expresses *in vivo* in a feline host cell a nucleic acid molecule having a sequence encoding feline immunodeficiency virus env protein; and a second plasmid that contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus gag and pro proteins.

14. The immunogenic composition of claim 11 wherein the plasmid further comprises a cytomeglovirus early (CMV-IE) promoter operatively linked to at least one of the nucleic acid molecule(s).

15. The immunogenic composition of claim 11 further comprising a live whole vaccine against a feline pathogen, or an inactivated whole vaccine against a feline pathogen, or recombinant vaccine against a feline pathogen, or a subunit vaccine against a feline pathogen.

16. A kit comprising (i) an immunogenic composition according to claim 11, and (ii) a feline vaccine selected from the group consisting of a live whole vaccine, an inactivated whole vaccine, a subunit vaccine, and recombinant vaccine.

17. A plasmid that contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins.

18. The plasmid according to claim 17 which contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env and gag and pro proteins.

19. The plasmid according to claim 17 which contains and expresses *in vivo* in a feline host cell a nucleic acid molecule having a sequence encoding feline immunodeficiency virus env protein.

20. The plasmid according to claim 17 which contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus gag and pro proteins.

21. A method for inducing in a feline host an immunological response against feline immunodeficiency virus comprising at least one plasmid that contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins.

22. The method according to claim 21 which comprises a plasmid that contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus env and gag and pro proteins.

23. The method according to claim 21 which comprises a first plasmid that contains and expresses *in vivo* in a feline host cell a nucleic acid molecule having a sequence encoding feline immunodeficiency virus env protein; and a second plasmid that contains and expresses *in vivo* in a feline host cell nucleic acid molecule(s) having sequence(s) encoding feline immunodeficiency virus gag and pro proteins.

24. The method of claim 21 wherein the plasmid further comprises a cytomeglovirus early (CMV-IE) promoter operatively linked to at least one of the nucleic acid molecule(s).

25. The method of claim 21 further comprising a live whole vaccine against a feline pathogen, or an inactivated whole vaccine against a feline pathogen, or recombinant vaccine against a feline pathogen, or a subunit vaccine against a feline pathogen.--

REMARKS

Provided herewith is a clean copy (see Exhibit 1) and a marked up copy (see Exhibit 2) of the Substitute Specification submitted under 37 CFR 1.125(a) to facilitate the Examiner's review of changes made to the specification. Furthermore the undersigned hereby affirms and confirms that no new subject matter is added by the attached Substitute Specification.

As to the sequence listing, it is stated that the sequence listing in this application is the same as in prior parent application Serial No. 09/232,278, filed January 16, 1999. It is respectfully requested that the U.S. PTO use the electronic version of the sequence listing in that prior application, making any necessary changes therein for this application, e.g., as to Serial Number and filing date; and, a copy of the hard copy of the sequence listing filed in that prior application is submitted herewith.

It is believed that the Sequence Listing conforms to the requirements of 37 C.F.R. §1.823(b). The Statements required by 37 C.F.R. §1.821(f) and (g) are set forth below.

Pursuant to 37 C.F.R. §1.821(g), the undersigned attorney of record hereby states that this submission, filed in accordance with 37 C.F.R. §1.821(g), does not contain new matter.

Pursuant to 37 C.F.R. §1.821(f), the undersigned attorney hereby states that the content of the paper copy submitted herewith, and the computer readable copy of the Sequence listing submitted in U.S. Serial No. 09/050,739, in accordance with 37 C.F.R. §1.821(c) and (e), respectively, are the same.

In view of the amendments, remarks and enclosures herewith, the application complies with the requirements for computer readable disclosure of the biological sequences under 37 C.F.R. §1.821-1.825.

Accordingly, early and favorable examination on the merits, and a telephone call from the Examiner are respectfully requested.

An early examination on the merits is solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By:



Thomas J. Kowalski
Reg. No. 32,147
Tel. (212) 588-0800

Enc. - Sequence Listing
- Abstract
- Substitute Specification

“Version with markings to show changes made”

Page 1, line 1:

This application is a divisional of prior application Serial No. 09/232,278, filed January 16, 1999 which is a continuation-in-part of copending International Application PCT/FR97/01315 having an international filing date of 15 July 1997, and designating the U.S. and claiming priority from French Application No. 96/09337, filed 19 July 1996. Reference is also made to the applications of Audonnet et al., Serial Nos. 09/232,468, 09/232,477, 09/232,279, 09/232,479, and 09/232,478 and to the application of Rijsewijk et al. Serial No. 09/232,469. All of the above-mentioned applications, as well as all documents cited herein and documents referenced or cited in documents cited herein, are hereby incorporated herein by reference. Vectors of vaccines or immunological compositions of the aforementioned applications, as well as of documents cited herein or documents referenced or cited in documents cited herein or portions of such vectors (e.g., one or more or all of regulatory sequences such as DNA for promoter, leader for secretion, terminator), may to the extent practicable with respect to the preferred host of this application, also be employed in the practice of this invention; and, DNA for vectors of vaccines or immunological compositions herein can be obtained from available sources and knowledge in the art, e.g., GeneBank, such that from this disclosure, no undue experimentation is required to make or use such vectors.

Page 1, line 37:

(See also U.S. Patent Nos. 5,846,946, 5,620,896, 5,643,578, 5,580,589, 5,589,466, 5,693,622, and 5,703,055; Science, 259:1745-49, 1993; Robinson et al., seminars in IMMUNOLOGY, 9:271-83, 1997; Luke et al., J. Infect. Dis. 175(1):91-97, 1997; Norman et al., Vaccine, 15(8):801-803, 1997; Bourne et al., The Journal of Infectious Disease, 173:800-7, 1996; and,

note that generally a plasmid for a vaccine or immunological composition can comprise DNA encoding an antigen operatively linked to regulatory sequences which control expression or expression and secretion of the antigen from a host cell, e.g., a mammalian cell; for instance, from upstream to downstream, DNA for a promoter, DNA for a eukaryotic leader peptide for secretion, DNA for the antigen, and DNA encoding a terminator.)

Page 1, line 6: Associations of vaccines against certain [canine] feline viruses have already been proposed in the past.

Page 2, line 3: The invention therefore proposes to provide a multivalent vaccine formula which makes it possible to ensure vaccination against a number of [canine] feline pathogenic viruses.

Page 7, line 23: [List of Figures] Brief Description of the Drawings.